



## **Prescription Drug Price Discrimination in Maine**

### **Drug Manufacturer Prices Are Higher for Humans than for Animals**

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**Prepared for U.S. Representative Tom Allen**

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U.S. House of Representatives**

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## **EXECUTIVE SUMMARY**

This report on prescription drug pricing was prepared at the request of U.S. Representative Tom Allen, who represents Maine. Rep. Allen asked the minority staff of the Committee on Government Reform to investigate two important questions relating to the pricing of human and animal drugs: (1) whether drug manufacturers who sell the same drug for both human use and animal use charge different prices for human use than for animal use; and (2) if the manufacturers are charging different prices, what impacts these pricing practices have on drug costs for consumers in Maine.

The report finds that drug manufacturers are engaging in substantial price discrimination, charging low prices for drugs when they are used by animals and high prices for the same drugs when they are used by seniors and other consumers who pay for their own drugs. The report also finds that drug prices for uninsured consumers in Maine could be significantly reduced if drug manufacturers eliminated this price discrimination.

This report investigates drug pricing at the manufacturer level. Its focus is the prices that drug manufacturers charge wholesalers of human and animal drugs rather than the prices that wholesalers charge pharmacists and veterinarians or the prices that pharmacists and veterinarians charge individual consumers. Because most animal drugs are purchased from veterinarians (who both prescribe and dispense medications) and not from pharmacists (who only dispense medications), the human and animal drug markets have substantially different characteristics at the retail level. Although retail-level price comparisons are analyzed in one part of this report, differences between the human and animal drug markets at the retail level make the two markets less comparable at the retail level than at the manufacturer level.

### **A. Methodology**

Many drugs that are approved and sold for human use are also approved and sold for animal use. Under the applicable FDA regulations, both the human and animal versions of the drugs must meet the same standards for quality and purity. This report investigates the pricing of two groups of drugs that are approved for both human and animal use. The animals that use these drugs include cattle, horses, dogs, and cats.

First, the report analyzes the pricing of popular brand name prescription drugs that are used by both humans and animals. These are drugs that meet the following criteria: (1) they are among the 200 most popular prescription drugs used by humans during 1998; (2) they are approved by FDA for both human and animal use; (3) they are dispensed to humans and animals for consumption through the same dosage route; and (4) they are commonly available by out-patient prescription. Eight drugs meet these criteria.

Among these eight popular drugs, some are sold in a different dosage to humans than animals, and several are made by different manufacturers for the human and animal markets. To determine if these factors affected the findings, the report analyzes a second group of drugs that are directly comparable in their human and animal versions. The drugs in the second group are brand name drugs that meet the following criteria: (1) they are approved by FDA for both human and animal use; (2) they are dispensed to humans and animals in the same dosage for consumption through the same dosage route; (3) they are manufactured for human and animal use by the same (or related) companies; and (4) they are commonly available for human use by out-

patient prescription. Eight drugs also meet these criteria. Two of these eight drugs – Lodine and Vasotec – are also in the first group of popular drugs.

## **B. Findings**

**Drug manufacturers charge substantially more for popular drugs when the drugs are used by humans than when the drugs are used by animals.** Eight brand name drugs among the top 200 are taken through the same dosage route by both humans and animals and are commonly obtained via out-patient prescription. For these eight popular drugs, drug manufacturers charge an average of 106% to 151% more when the drug is intended for human use than when the drug is intended for animal use. This means that the average manufacturer-level price for human use is more than twice as much as the manufacturer-level price for animal use.

**Drug manufacturers charge substantially more for directly comparable drugs when the drugs are used by humans than when the drugs are used by animals.** Similar results were obtained when the report examined the pricing of the eight brand name drugs that are made for the human and animal markets in the same dosages by the same (or related) companies. For this group of eight directly comparable drugs, manufacturers charge an average of 131% more when the drug is intended for human use than when the drug is intended for animal use. This price differential is similar to the price differential observed for the eight popular drugs.

**In dollar terms, the price differential can be substantial.** The drug with the largest price differential in dollar terms is Lodine, a popular arthritis medicine used by both humans and dogs. American Home Products charges \$108.90 for a one-month supply of Lodine when the drug is to be used by humans, but only \$37.80 when the drug is to be used by dogs. Another drug with a large price difference is Vasotec, a high blood pressure medication that was the 14th most frequently prescribed human drug in the United States in 1998. Merck charges \$78.55 for a one-month supply when the drug is to be used by humans, but only \$51.30 when the drug is to be used by dogs – an annual difference of over \$325.

**Drug prices for uninsured consumers in Maine could be significantly reduced by preventing price discrimination.** Based on a survey of pharmacists in Rep. Allen's district, the report calculates an upper-bound estimate of the potential savings to individuals who must pay for their own drugs, such as senior citizens without prescription drug coverage, from eliminating price discrimination. If the eight popular drugs analyzed in this report were sold by manufacturers at the same prices for human use that they are currently sold for animal use, the prices of these drugs for uninsured consumers in Maine could be reduced by an average of 25% to 37%.

**The price differentials cannot be adequately explained by quality differences or research costs.** The price differentials observed in this report appear to be directly attributable to the deliberate pricing strategies of the drug manufacturers. The report analyzes whether differences in drug quality, drug production costs, or research and development expenses are likely causes of the price differentials. None of these factors appears to account adequately for the discriminatory pricing practices found in the report.

## I. THE IMPACT OF HIGH DRUG PRICES

Prescription drug costs are rising and causing increasing hardship for consumers who must pay for their own drugs. In 1990, prescription drug expenditures in the United States were \$37.7 billion dollars.<sup>1</sup> By 1998, prescription drug expenditures had more than doubled to \$93.4 billion, due to a combination of price increases and increased utilization.<sup>2</sup> From 1992 to 1997, prescription drug expenditures rose by more than 11% annually.<sup>3</sup> Reducing the costs of prescription drugs has become a national issue, with numerous proposals pending in Congress.

Much of the discussion of this issue has focused on the plight of senior citizens, who make up 12% of the population, but use one-third of all prescription drugs.<sup>4</sup> Although the elderly have the greatest need for prescription drugs, they often have the most inadequate insurance coverage for drugs. With the exception of drugs administered during inpatient hospital stays, Medicare generally does not cover prescription drugs. According to a recent analysis by the National Economic Council, approximately 75% of Medicare beneficiaries lack dependable, private-sector prescription drug coverage.<sup>5</sup> A recent study by federal researchers found that 35% of Medicare recipients – over 13 million seniors – do not have any insurance coverage for prescription drugs.<sup>6</sup>

Because of the high costs of prescription drugs, uninsured consumers in general – and seniors in particular – face enormous hardships paying for the medications they need. A recent study found that prescription drug expenditures are the single largest out-of-pocket health care cost

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<sup>1</sup> Health Care Finance Administration, *National Health Expenditures* (1999) (online at [www.hcfa.gov/stats/nhe-oact/tables/t10.htm](http://www.hcfa.gov/stats/nhe-oact/tables/t10.htm)).

<sup>2</sup> National Institute for Health Care Management Foundation, *Factors Affecting the Growth of Prescription Drug Expenditures* (July 9, 1999).

<sup>3</sup> *National Health Expenditures*, *supra* note 1.

<sup>4</sup> Senate Special Committee On Aging, *Developments in Aging: 1993*, 103d Cong., 2d Sess. 35 (1994) (S. Rpt. 403).

<sup>5</sup> National Economic Council, Domestic Policy Council, *Disturbing Truths and Dangerous Trends: The Facts About Medicare Beneficiaries and Prescription Drug Coverage* (July 22, 1999). In this study, private sector retiree coverage was considered to be the only dependable form of private-sector prescription drug coverage for senior citizens. Other sources of coverage, such as Medigap coverage or Medicare managed care plans were not considered dependable because the plans are often expensive, inaccessible, or inadequate.

<sup>6</sup> Health Affairs, *Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries*, 237 (Jan./Feb. 1999).

for senior citizens on Medicare.<sup>7</sup> Approximately 4.5 million senior citizens spend over \$1,000 annually on prescription drugs, a significant burden for individuals living on a fixed income.<sup>8</sup> Indeed, one study found that more than one in eight seniors are forced to choose between buying food and paying for prescription drugs.<sup>9</sup> As a consequence of high drug prices, millions of senior citizens and other uninsured consumers must go without necessary medications, skip doses, or take less than their prescribed doses, thereby endangering their health.

## II. OBJECTIVE OF THE STUDY

One of the root causes of high drug prices is manufacturer price discrimination. In 1998, the Congressional Budget Office (CBO) conducted a detailed examination of drug pricing. CBO found that drug manufacturers engage in price discrimination that forces uninsured consumers to pay the highest prices for drugs. According to CBO:

Different buyers pay different prices for brand-name prescription drugs. . . . In today's market for outpatient prescription drugs, purchasers that have no insurance coverage for drugs . . . pay the highest prices for brand name drugs.<sup>10</sup>

In March 1999, the Federal Trade Commission (FTC) released a comprehensive analysis of prescription drug pricing that reached a similar conclusion. As in the CBO study, the FTC study found that drug manufacturers engage in price discrimination. According to the FTC:

A notable example of differential pricing is the so-called "two tiered pricing structure" under which pharmaceutical companies set lower prices to large buyers like hospitals, HMOs, and PBMs, and charge higher prices to other buyers that include the uninsured and independent and chain retail pharmacies.<sup>11</sup>

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<sup>7</sup> AARP Public Policy Institute, *Out-of-Pocket Health Spending by Medicare Beneficiaries Age 65 and Older: 1999 Projections* (Dec. 1999).

<sup>8</sup> See National Economic Council, Domestic Policy Council, *Disturbing Truths and Dangerous Trends: The Facts About Medicare Beneficiaries and Prescription Drug Coverage*, *supra* note 5; Soumerai, Steven, *Inadequate Prescription-Drug Coverage for Medicare Enrollees – A Call to Action*, New England Journal of Medicine (Mar. 1999).

<sup>9</sup> Families USA Foundation, *Worthless Promises: Drug Companies Keep Boosting Prices* 6 (March 1995).

<sup>10</sup> Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, xi (July 1998).

<sup>11</sup> Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, 75 (Mar. 1999).

While these and other independent experts have concluded that drug manufacturers engage in price discrimination, there have been few analyses that quantify the extent of this discrimination. The other two reports to quantify the extent of this price discrimination in Maine were released by Rep. Allen. These reports showed that (1) uninsured senior citizens in Maine pay over twice as much for prescription drugs as favored customers like HMOs and the federal government,<sup>12</sup> and that (2) uninsured senior citizens in Maine also pay far higher prices than do purchasers in Canada and Mexico.<sup>13</sup>

This study seeks to quantify the extent of price discrimination in a third way. It compares the prices that drug manufacturers charge for drugs used by humans with the prices that the manufacturers charge for the same drugs when used by animals. It is the first study to estimate the effect of this type of price discrimination on drug costs for uninsured consumers in Maine, such as senior citizens who pay for their own drugs.

### III. METHODOLOGY

#### A. Selection of Drugs

Approximately 37,000 prescription drug products in the United States are approved for human consumption.<sup>14</sup> These 37,000 drugs contain approximately 2,500 different active ingredients.<sup>15</sup> In 1998, drug manufacturers sold almost \$100 billion worth of these pharmaceuticals for use in the United States.<sup>16</sup>

The animal drug market is smaller, but is growing rapidly. Over 1,500 drug products in the United States are approved for animal consumption.<sup>17</sup> These drugs contain approximately 400 different active ingredients.<sup>18</sup> Drug manufacturers are continuing to seek approval for new drugs

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<sup>12</sup> Minority Staff Report of the House Committee on Government Reform and Oversight, *Prescription Drug Pricing in the 1st Congressional District in Maine: Drug Companies Profit at the Expense of Older Americans* (Oct. 1998).

<sup>13</sup> Minority Staff Report of the House Committee on Government Reform and Oversight, *Prescription Drug Pricing in the 1st Congressional District in Maine: An International Price Comparison* (Oct. 1998).

<sup>14</sup> FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (1999).

<sup>15</sup> *Id.*

<sup>16</sup> *Factors Affecting the Growth of Prescription Drug Expenditures*, *supra* note 2.

<sup>17</sup> FDA, *FDA Approved Animal Drug Products* (1999).

<sup>18</sup> *Id.*

for the animal market, particularly for companion animals.<sup>19</sup> In 1998, drug manufacturers sold approximately \$3.1 billion worth of pharmaceuticals for animal use.<sup>20</sup>

There is a substantial overlap between drugs approved for human and animal use. Of the approximately 400 active ingredients found in animal drugs, approximately 80 are approved by the Food and Drug Administration for use by both humans and animals. In total, about 400 animal drugs contain active ingredients that are also found in human drugs. In many other cases, veterinarians prescribe products that are approved for human use for use in animals.<sup>21</sup>

This study analyzed two sets of brand name drugs. The first set of drugs is comprised of popular brand name drugs that are manufactured for both human and animal use. The second set of drugs is comprised of brand name drugs that are directly comparable in their human and animal versions.<sup>22</sup>

## **1. Popular Drugs**

The first set of drugs analyzed in this report are brand name drugs that meet the following criteria: (1) the drug is among the 200 most popular drugs used by humans during 1998; (2) the drug is approved by FDA for both human and animal use; (3) the drug is dispensed to humans and animals for consumption through the same dosage route;<sup>23</sup> and (4) the drug is commonly available

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<sup>19</sup> See Tanouye, Elyse, Wall Street Journal, *The Ow in Bowwow: With Growing Market in Pet Drugs, Makers Revamp Clinical Trials* (Apr. 13, 1999).

<sup>20</sup> Animal Health Institute, *Press Release: Animal Health Product Sales Rise to \$4.3 Billion in 1998* (July 31, 1998).

<sup>21</sup> For example, Prozac is prescribed by some veterinarians to treat anxiety disorders in dogs. See *The Ow in Bowwow: With Growing Market in Pet Drugs, Makers Revamp Clinical Trials*, *supra* note 19. FDA regulations allow veterinarians to prescribe a human-approved drug for animal use, provided that a product containing the same active ingredient has not also been approved for use in animals.

<sup>22</sup> This report focused on brand name drugs because manufacturers of brand name drugs generally have greater control over drug pricing than manufacturers of less expensive generic drugs. Several of the drugs included in the survey, however, are also available in generic versions. Consumers who purchase these drugs in their generic version are likely to pay less than those who purchase the brand name version. The Congressional Budget Office has found that the availability of a generic drug often does not decrease the cost of the brand name product. See *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, *supra* note 10.

<sup>23</sup> Sometimes, the same drug may be taken by humans and animals through different dosage routes. For example, the drug may be taken orally by humans (through a tablet or capsule) and by injection by animals. Only drugs that are taken through the same dosage route



for human use by out-patient prescription. Drug popularity was determined based on the 1998 listings by *Pharmacy Times* of (1) the top 200 drugs ranked by dollar sales and (2) the top 200 drugs ranked by number of prescriptions filled.<sup>24</sup> Any drug on either list was considered to be one of the top 200 drugs used by humans in 1998.

The following eight drugs meet these four criteria:

- C Amoxil, which is manufactured by SmithKline Beecham for sale to the human market and by A.H. Robbins for sale to the animal market under the brand name Robamox. Amoxil is an antibiotic and was the 45th most frequently prescribed human drug in the United States in 1998. The product is approved on the animal market as an antibiotic to treat dogs and cats.
- C Augmentin, which is manufactured by SmithKline Beecham for sale to the human market and by Pfizer for sale to the animal market under the brand name Clavamox. Augmentin is an antibiotic and was the 12th best selling human drug in dollar sales in the United States in 1998. The product is approved on the animal market as an antibiotic to treat dogs and cats.
- C Bactroban, which is manufactured by SmithKline Beecham for sale to the human market and by Pfizer for sale to the animal market under the brand name Bactoderm. Bactroban is a topical antibiotic and was the 121st most frequently prescribed human drug in the United States in 1998. The product is approved on the animal market to treat infections in dogs.
- C Lanoxin, which is manufactured by Glaxo Wellcome for sale to the human market and by Evsco for sale to the animal market under the brand name Cardoxin LS. Lanoxin is used to treat heart failure in humans and was the 9th most frequently prescribed human drug in the United States in 1998. The product is approved on the animal market to treat heart failure in dogs.
- C Lasix, which is manufactured by Hoechst-Marion Roussel. Lasix is used to treat high blood pressure and heart problems in humans and was the 160th most frequently prescribed human drug in the United States in 1998. The product is approved on the animal market to treat edema in cattle, dogs, and cats.
- C Lodine, which is manufactured by Wyeth-Ayerst, a subsidiary of American Home Products, for sale to the human market and by Fort Dodge, another subsidiary of American Home Products, for sale to the animal market under the brand name Etogesic. Lodine is used to treat arthritis in humans and was the 143rd best selling human drug in dollar sales

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are included in this analysis to increase the comparability of the drugs.

<sup>24</sup> Pharmacy Times, *The Top 200 Drugs of 1998* (1999) (online at <http://www.pharmacytimes.com/top200.html>).

in the United States in 1998. The product is approved on the animal market to treat arthritis in dogs.

- C     Stadol, which is manufactured by Bristol-Myers Squibb for sale to the human market and by a subsidiary of American Home Products for sale to the animal market under the brand names Torbutrol and Torbugesic. Stadol is used as a pain reliever in humans and was the 195th best selling human drug in dollar sales in the United States in 1998. The product is approved on the animal market as a pain reliever in dogs and horses.
- C     Vasotec, which is manufactured by Merck for sale to the human market and by Merial, a subsidiary, for sale to the animal market under the brand name Enacard. Vasotec is used to treat high blood pressure in humans and was the 14th most frequently prescribed human drug in the United States in 1998. The product is approved on the animal market to treat heart failure in dogs.

## **2.     Directly Comparable Drugs**

Among the eight popular drugs, three (Lasix, Amoxil, and Bactroban) are manufactured in different dosages for the two markets.<sup>25</sup> In addition, five drugs (Amoxil, Augment, Bactroban, Lanoxin, and Stadol) are made by different manufacturers for the two markets. In order to determine if these factors account for the observed price differentials, a second group of brand name drugs that are directly comparable in their human and animal versions was also analyzed in this report. These drugs were chosen based on the following criteria: (1) the drug is approved by FDA for use in both humans and animals; (2) the drug is dispensed to humans and animals in the same dosage for consumption through the same dosage route; (3) the drug is manufactured by the same company (or by affiliates, subsidiaries, or partners of the same company) for both the human and animal markets; and (4) the drug is commonly available for human use by out-patient prescription.

Eight drugs meet these four criteria. Two of these eight – Lodine and Vasotec – are also included in the list of popular drugs. The six additional drugs that meet the four criteria are:

- C     Cleocin, which is manufactured by Pharmacia and Upjohn and sold in the animal market under the brand name Antirobe. Cleocin is an antibiotic used to treat bacterial infections in humans. The product is approved on the animal market to treat bacterial infections in dogs.
- C     Fulvicin U/F, which is manufactured by Schering Plough. Fulvicin U/F is antifungal agent used to treat infections of the skin, hair, and scalp in humans. The product is approved on the animal market as an antifungal medication in dogs and cats.

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<sup>25</sup> Lasix is sold in 20 mg. tablets for the human market and in 12.5 mg. tablets for the animal market. Amoxil is sold in 250 mg. capsules for the human market and 200 mg. capsules for the animal market. Bactroban is sold in 30 gram tubes for the human market and 15 gram tubes for the animal market.

- C Medrol, which is manufactured by Pharmacia and Upjohn. Medrol is used to treat arthritis, allergies, and asthma in humans. The product is approved on the animal market as an anti-inflammatory medication in dogs and cats.
- C Robaxin, which is manufactured by A.H. Robins. Robaxin is used as an anti-inflammatory pain reliever in humans. The product is approved on the animal market for use as a pain reliever in dogs and cats.
- C Robinul, which is manufactured by A.H. Robins. Robinul is used in treatment of peptic ulcers in humans. The product is approved on the animal market as a pre-anaesthetic agent for use in dogs and cats.
- C Winstrol, which is manufactured by Sanofi.<sup>26</sup> Winstrol is used to treat end stage renal disease, anemia, angioedema, and chronic weight loss following major surgery in humans. The product is approved on the animal market to treat weight loss, debility, and other symptoms associated with old age or trauma in dogs and cats.

## **B. Determination of Manufacturer-Level Prices for Humans**

This report calculates the prices that drug manufacturers charge for human drugs based on the Wholesale Acquisition Cost (WAC) that human drug wholesalers pay to acquire drugs for sale to pharmacists. WAC prices represent the average price that drug manufacturers charge human drug wholesalers for products that are intended for resale to pharmacists. WAC prices do not include rebates or other forms of discounts that favored customers like HMOs often receive.

The prices paid by pharmacists for drugs are slightly higher than the prices charged by the drug manufacturers to wholesalers, because the prices paid by pharmacists incorporate a markup by the drug wholesaler. Typical wholesale markups are small, about 2% to 4% above WAC.<sup>27</sup>

## **C. Determination of Manufacturer-Level Prices for Animals**

To determine the prices that drug manufacturers charge for drugs used by animals, the minority staff obtained the prices that animal drug wholesalers sell the drugs investigated in this report to veterinarians. Staff obtained these prices for five major animal drug wholesalers and determined an average price that animal drug wholesalers charge veterinarians for each of the

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<sup>26</sup> Although Winstrol is manufactured by Sanofi, it is sold by Pharmacia and Upjohn on the animal market. Pharmacia and Upjohn, *Animal Health Products: Winstrol-V* (1999) (online at [www.pnuanimalhealth.com/product/companimal/winstf2.html](http://www.pnuanimalhealth.com/product/companimal/winstf2.html)).

<sup>27</sup> Patricia M. Danzon, *Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross-National Studies* (April 1999).

drugs. To determine the manufacturer-level price for the drugs, these average wholesale-level prices were adjusted to eliminate the effect of the markup charged by animal drug wholesalers.<sup>28</sup>

Two drugs of the drugs examined in this report are not sold to veterinarians through animal drug wholesalers, but are purchased by veterinarians directly from the drug manufacturer. The prices that the manufacturer charges for these two drugs were obtained by the minority staff. No adjustment was made to account for the effect of a wholesale markup since these prices were already manufacturer-level prices.

#### **D. Comparison of Manufacturer-Level Prices**

Drug selection for this analysis was based on criteria that were designed to minimize the differences, if any, between the human and animal versions of drugs being compared. All drugs in this analysis are sold in the same dosage route to both the human and animal markets. Whenever possible, the drug dosages that are analyzed are identical in both the human and animal markets.<sup>29</sup> This was the case with all of the drugs analyzed in this report except for Lasix, Amoxil, and Bactroban. For these drugs, the closest dosage sizes available in the two markets were chosen for comparison. The dosages used in this study are shown in Appendices A and B.

Once a dosage size was selected, price comparisons were based on the price of a typical one month supply of the product for human consumers. Information on typical quantities prescribed by physicians was obtained from the *Physicians Desk Reference* or from the *U.S. Pharmacopeia Dispensing Information*.

For drugs sold in the same dosage for human and animal use, the price comparisons could be made based on the price per tablet or capsule. For the other drugs, prices were compared based on the cost per gram of active drug ingredient for the closest dosage sizes available in the human and animal markets.

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<sup>28</sup> The report adjusted for the wholesale markup by reducing the average wholesale-level price by 3%. This represents the midpoint of the markup that human wholesalers typically charge pharmacies. See *Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross-National Studies*, *supra* note 27. Because the veterinary market is smaller than the human market, it is possible that wholesalers of animal drugs charge a higher markup than wholesalers of human drugs. If animal drug wholesalers charge higher markups than human drug wholesalers, the actual manufacturer-level prices for animal uses would be lower than the level reported in this study. This would make the actual level of manufacturer price discrimination higher than reported in this study.

<sup>29</sup> In some cases, the drugs analyzed in the report are sold in a range of different dosages on the human market. For example, Lodine is sold for humans in dosages of 200, 300, 400, and 500 mg. In these cases, prices were compared based on the closest dosages available in both the human and animal markets. In the case of Lodine, the drug is only available in the 300 mg. dosage for animals. Thus, for purposes of the price comparisons in this report, the price comparison is based on the 300 mg. human version of Lodine.

## **E. Evaluation of Impacts on Uninsured Consumers**

To determine the effect that manufacturer-level price differentials could have on prices paid by uninsured consumers in Maine, the minority staff and the staff of Rep. Allen surveyed drug prices in eight pharmacies, including both chain and independent pharmacies, in Rep. Allen's district. Rep. Allen represents the 1st Congressional District of Maine, which includes Portland and the surrounding communities.

## **III. RESULTS OF PRICE COMPARISONS**

### **A. Manufacturer Prices Are Over Twice as High for Humans as for Animals**

#### **1. Price Differentials for Popular Prescription Drugs**

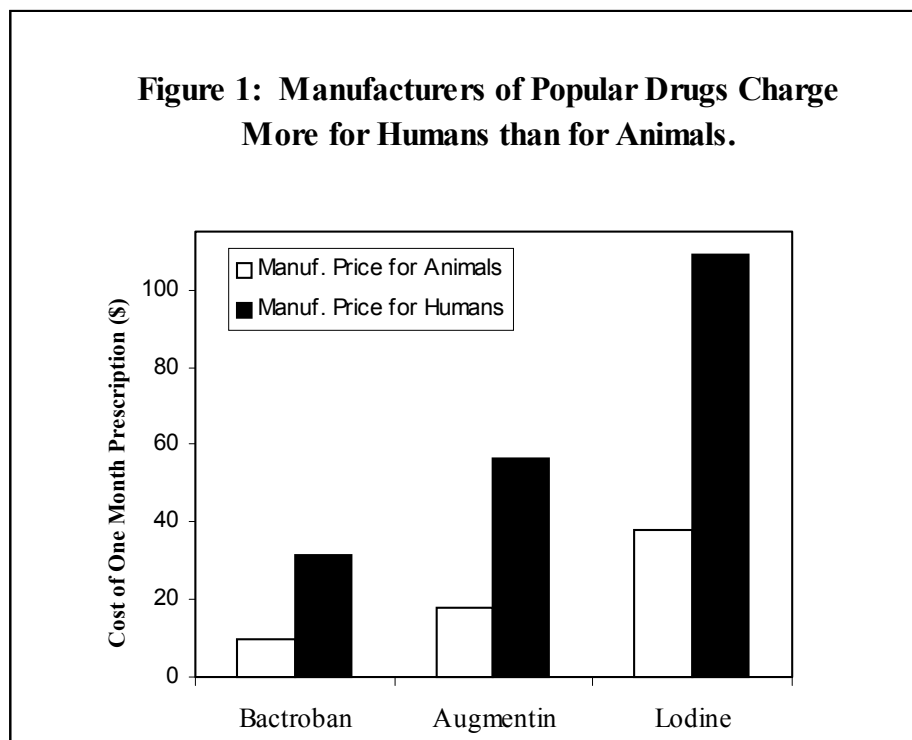
Eight brand name drugs among the top 200 human drugs are approved for use through the same dosage route for both humans and animals and are commonly obtained for human use via out-patient prescription. For these eight popular drugs, drug manufacturers charge far more when the intended end-users are humans than when the intended end-users are animals. The average differential between the price at which the drugs are sold by manufacturers for human use and the price at which the drugs are sold by manufacturers for animal use is 106% to 151%. This means that drug manufacturers charge more than twice as much for these drugs when sold for use by humans as they charge when the drugs are sold for use by animals (Table 1).

**Table 1: Drug Manufacturers Charge More for Popular Drugs Used by Humans than for the Same Drugs Used by Animals.**

Drug Name	Manufacturer of Human Version	Human Use	Manufacturer Price (One Month Supply)		Price Differential
			Animal Market	Human Market	
Bactroban	SmithKline Beecham	Antibiotic	\$9.98	\$31.56	216%
Augmentin	SmithKline Beecham	Antibiotic	\$18.00	\$56.40	213%
Lodine	American Home Products	Arthritis	\$37.80	\$108.90	188%
Stadol	Bristol Myers Squibb	Pain Relief	\$25.48	\$61.11	140%
Lasix	Hoechst Marion Roussel	High Blood Pressure	\$4.80	\$9.60	100%
Vasotec	Merck	High Blood Pressure	\$51.30	\$78.55	53%
Lanoxin	Glaxo Wellcome	Heart Failure	\$6.36	\$25.65 (\$4.08)	303% (-56%)
Amoxil	SmithKline Beecham	Antibiotic	\$16.20	\$15.30	-6%
Average for Eight Drugs					151% (106%)

Three drugs with high price differentials in percentage terms are Bactroban, Augmentin, and Lodine (Figure 1). Bactroban and Augmentin, which are manufactured by SmithKline Beecham for the human market, are both antibiotics. Both had price differentials of over 200%, which means that the manufacturer-level price for these drugs is over three times more expensive when the drug is intended for human use than when the drug is intended for animal use.

Lodine is an arthritis medication. A common prescription for Lodine is ninety 300 mg. capsules. Fort Dodge, a subsidiary of American Home Products, sells this quantity of Lodine for only \$37.80 when the intended end-users are dogs or cats. But when the intended end-users are humans, Wyeth-Ayerst, another subsidiary of American Home Products, sells the same quantity of the drug for \$108.90 -- a price differential of 188%.



Two different price differentials are presented in this report for Lanoxin, a medication used to treat heart failure in both humans and dogs. For the animal market, Lanoxin is manufactured in a liquid form. For the human market, it is manufactured in both a liquid form and a tablet form. For this drug, the most direct price comparison is a liquid-to-liquid comparison between the manufacturer-level price for the liquid version of the drug for animals (\$6.36) and the manufacturer-level price for the liquid version of the drug for humans (\$25.65). This “apples to apples” comparison results in a price differential of 303%, the highest price differential in percentage terms among the popular drugs analyzed in this report.

It is also possible, however, to compare the price of the liquid version of the drug for animals with the price of the tablet version for humans by calculating costs per gram of active drug ingredient. Although this approach can be criticized as an “apples to oranges” comparison, it is also included in this analysis in an effort to be conservative. The manufacturer-level price for the human version of the same quantity of the drug in tablet form (\$4.08) is less than the

manufacturer-level price of either the liquid version of the drug for animals or the liquid version of the drug for humans, producing a human to animal price differential of -56%.<sup>30</sup>

The only popular drug for which the manufacturer-level price is less expensive for humans than for animals in a direct “apples to apples” comparison is Amoxil. For this drug, which is manufactured by SmithKline Beecham for the human market, the manufacturer-level price is 6% lower for the human market than for the animal market.

## **2. Price Differentials for Directly Comparable Prescription Drugs**

This report found similar results when analyzing the pricing of directly comparable drugs: manufacturers charge significantly more for directly comparable brand name drugs when the drugs are used by humans than when the drugs are used by animals. There are eight brand name drugs that are approved for use in the same dosage in both humans and animals, are manufactured for both markets by the same (or related) companies, and are commonly obtained for human use via out-patient prescription. For these eight products, the average differential between the price at which the drug is sold by the manufacturer for human use and the price at which the drug is sold by the manufacturer for animal use is 131% (Table 2). This price differential is similar to the average price differential observed for the eight popular drugs. For both sets of drugs, manufacturers charge an average of more than twice as much when a drug is sold for use by humans than they charge when the same drug is sold for use by animals.

Among the directly comparable drugs, Medrol, which is manufactured by Pharmacia and Upjohn, has the highest price differential: 415%. This drug is used to treat arthritis, asthma, and allergies in humans and is used as an anti-inflammatory agent in dogs and cats. Pharmacia and Upjohn charges \$20.10 for a one month supply of Medrol when the end-user is a person seeking treatment for arthritis, but only \$3.90 for the same quantity of Medrol when the end-user is a dog. Winstrol, which is manufactured by Sanofi, has the second highest price differential: 256%. This drug is used to treat end-stage renal disease and anemia in humans and weight loss, debility, and other symptoms associated with old age in dogs and cats. Sanofi sells this drug for \$19.20 when the end-users are humans, but only \$5.40 when the end-users are animals.

**Table 2: Drug Manufacturers Charge More for Directly Comparable Drugs When the**

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<sup>30</sup> A similar cost-per-gram analysis comparing the price of the tablet form of a drug to the price of the liquid form could also be done in the case of Lasix, which is sold in tablet form for animals and in both tablet form and liquid form for humans. In the case of Lasix, including this “apples to oranges” comparison would have the opposite effect: it would substantially increase the price differential between the animal and human versions of the drug. This analysis was not included in the report.

## Drugs Are Used by Humans than When the Drugs Are Used by Animals.

Drug Name	Manufacturer	Human Use	Manufacturer Price (Monthly Supply)		Price Differential
			Animal Market	Human Market	
Medrol	Pharmacia and Upjohn	Arthritis; Allergies; Asthma	\$3.90	\$20.10	415%
Winstrol	Sanofi	Anemia; Renal Disease	\$5.40	\$19.20	256%
Lodine	American Home Products	Arthritis	\$37.80	\$108.90	188%
Robaxin	A.H. Robins	Pain Relief	\$15.00	\$31.20	108%
Vasotec	Merck/Merial	High Blood Pressure	\$51.30	\$78.55	53%
Cleocin	Pharmacia and Upjohn	Antibiotic	\$17.10	\$22.20	30%
Robinul	A.H. Robins	Ulcers	\$29.40	\$29.98	2%
Fulvicin U/F	Schering	Antifungal	\$38.40	\$36.60	-5%
<b>Average for Eight Drugs</b>					<b>131%</b>

Overall, manufacturers charge more for seven of the eight directly comparable drugs when the end users are humans than they charge when the end users are animals. The only drug that was less expensive at the manufacturer-level for humans than for animals was Fulvicin U/F, which is manufactured by Schering.

### **B. Price Differentials Can Be Substantial in Dollar Terms**

These price differences can translate into large differences in dollar terms. Two of the drugs surveyed in this report, Lodine and Vasotec, are both popular (among the top 200 human drugs in 1998) and directly comparable (manufactured in the same dosage route and dosage by the same or related companies in both the human and animal markets). Both have large price differentials in dollar terms.

Lodine, the arthritis medication made by subsidiaries of American Home Products, has the largest price differential in dollar terms observed in this report. The manufacturer sells a monthly prescription of this drug for \$108.90 for human use -- more than \$70 more than the manufacturer charges when selling the same quantity of the drug for use by dogs or cats.

Similarly, Vasotec, the 14th most prescribed human drug in 1998, has a large dollar value price differential. Merck sells a one-month supply of Vasotec for \$78.55 when the intended users are human, while Merial, a Merck subsidiary, charges only \$51.30 -- over \$25 less -- when the intended users are animals. Vasotec treats a chronic condition (high blood pressure) and is often taken over long periods by senior citizens and others. On an annual basis, the manufacturer-level price differential for Vasotec is over \$325.

### **C. Retail-Level Price Differentials Between Human and Animal Drugs Can Be Significant**



This analysis focuses primarily on the prices that drug manufacturers charge wholesalers of human and animal drugs, not the prices that wholesalers charge pharmacists and veterinarians or the prices that pharmacists and veterinarians charge individual consumers. In the case of comparisons of human and animal drugs, a manufacturer-level price comparison provides a more direct comparison than a retail-level price comparison because of the differing nature of the retail market for human and animal drugs. Human drugs are prescribed by a doctor and dispensed by a pharmacist. In contrast, most animal drugs are both prescribed and dispensed by the veterinarian. Because they serve both functions, veterinarians often incorporate some of the costs of practicing veterinary medicine into their prices for prescription drugs, resulting in markups that are many times higher than pharmacists charge.

Because of these complexities, the most direct comparison of retail-level prices can be obtained by comparing the prices that pharmacists charge human consumers with the prices that specialized veterinary pharmacies charge animal owners. Through the Internet and mail order, the minority staff identified three veterinary pharmacies that resemble human pharmacies in that they dispense, but do not prescribe, medications.<sup>31</sup> These veterinary pharmacies sell seven of the eight popular drugs investigated in this report. The report compared the average prices that these veterinary pharmacies charge for the drugs with the average retail prices that consumers in Maine must pay for the same drugs.

This analysis showed that there is a substantial difference between what consumers in Maine must pay for these seven drugs and the prices that animal owners can pay to acquire the drugs from veterinary pharmacies.<sup>32</sup> On average, it costs consumers in Maine 116% to 209% more for these drugs than animal owners (Table 3). This means that uninsured consumers in Maine, such as senior citizens without prescription drug coverage, are being forced to pay on average two to three times as much as animal owners to acquire these drugs.

**Table 3: Retail-Level Prices Are More Expensive for Human Consumers in Maine than for Animal Owners.**

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<sup>31</sup> The three veterinary pharmacists were KV Vet Supply, Vet Warehouse, and Lambriar Animal Health.

<sup>32</sup> Average retail prices for the tablet human version of Lanoxin were not collected in Rep. Allen's district. As a substitute, the report uses the price at which the tablet version of Lanoxin is available through a major Internet pharmacy. Generally, prices in Rep. Allen's district are slightly higher than prices available at this Internet pharmacy.

Drug	Average Retail Price (Monthly Supply)		Price Differential (%)
	Price at Veterinary Pharmacy	Retail Price for Humans	
Bactroban	\$14.50	\$48.30	233%
Lasix	\$5.37	\$15.64	191%
Augmentin	\$25.84	\$66.29	157%
Amoxil	\$15.29	\$34.95	129%
Lodine	\$65.25	\$143.24	120%
Lanoxin	\$5.41	\$39.31 (\$4.39)	627% (-23%)
Vasotec	\$91.41	\$97.53	7%
<b>Average Price Differential</b>			<b>209% (116%)</b>

#### IV. DRUG PRICES FOR UNINSURED CONSUMERS IN MAINE COULD BE SIGNIFICANTLY REDUCED BY PREVENTING PRICE DISCRIMINATION

The price comparisons described in part III show that drug manufacturers charge different prices for drugs intended for human use than for drugs intended for animal use. This part assesses the impact that this manufacturer-level price discrimination has on human drug prices for consumers in Maine.

To make this assessment, the report estimates the potential cost savings for consumers in Maine if drug manufacturers did not engage in price discrimination and instead charged the same price for human drugs that they now charge for animal drugs. Experts state that drug wholesalers and retail pharmacies are highly competitive and are likely to pass any cost savings on to consumers. According to Professor Stephen W. Schondelmeyer, “[a]ny discounts passed on to community pharmacies will be passed on to the consumer, or payor, of the prescription because of the competitive retail environment.”<sup>33</sup> For this reason, the analysis assumes that the reductions in the manufacturer-level price will be passed on to the pharmacist by the human drug wholesaler and to the consumer by the pharmacist.

Under these circumstances, the potential savings would be substantial for consumers in Maine who purchase their own drugs, such as senior citizens without prescription drug insurance. For example, the average retail cost of purchasing a one month supply of the blood pressure medication Vasotec in Maine is \$97.53. If this price were reduced by \$27.25, which is the difference between the manufacturer-level price for human use and the manufacturer-level price for animal use, a consumer in Maine would pay only \$70.28 for a one-month supply. On an annual basis, the consumer in Maine would save over \$325.

In dollar terms, consumers in Maine who purchase Lodine would realize the greatest savings. Their drug costs would drop by over \$70 for a one-month supply. Table 4 summarizes

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<sup>33</sup> Schondelmeyer, Stephen W., PRIME Institute, University of Minnesota, *Competition and Pricing Issues in the Pharmaceutical Market*, University of Minnesota, 12 (Aug. 1994).

the potential savings for each of the eight popular drugs analyzed in this report. The average savings for the eight popular drugs would be 25% to 37%.

**Table 4: Consumers in Maine Could Save Hundreds of Dollars if Drug Manufacturers Did Not Engage in Price Discrimination.**

Drug	Average Retail Price in Maine (Monthly Supply)	Potential Savings (Dollars)	Potential Savings (%)
Augmentin	\$66.29	\$38.40	58%
Lodine	\$143.24	\$71.10	50%
Bactroban	\$48.30	\$21.58	45%
Stadol	\$88.92	\$35.63	40%
Lasix	\$15.64	\$4.80	31%
Vasotec	\$97.53	\$27.25	28%
Lanoxin	\$39.31 (\$4.39)	\$19.29 (-\$2.28)	49% (-52%)
Amoxil	\$34.95	-\$0.90	-3%
<b>Average Savings</b>			<b>37% (25%)</b>

These estimates of the potential savings for uninsured consumers in Maine should be considered upper-bound estimates. The estimates assume that drug manufacturers sell their products to human drug wholesalers at the same price that they are now selling their products to animal drug wholesalers. In reality, drug manufacturers could choose to sell to both markets at a price between their current animal and human prices. Moreover, representatives of the drug manufacturers have argued that pharmacists would not pass along all of the cost savings to uninsured consumers. These factors could reduce the potential savings.

## **V. QUALITY DIFFERENCES AND RESEARCH COSTS DO NOT APPEAR TO EXPLAIN THE PRICE DIFFERENTIALS**

This report examined several possible explanations for the substantial manufacturer-level price differences observed between the drugs intended for human use and the drugs intended for animal use. The most probable explanation appears to be that price discrimination is a central component of the drug manufacturers' pricing strategies.

### **A. Drug Quality and Production Costs**

It appears unlikely that differences in drug quality can explain the results observed in this study. The Food and Drug Administration regulations governing drug quality and production, the so-called "good manufacturing practice" (GMP) requirements, are codified in 21 C.F.R. part 211. These requirements, which are designed to ensure drug quality and consistency, apply equally to both human and animal drugs. According to FDA:

The methods, facilities, and controls under which animal drugs are manufactured, processed, packaged, or held for sale must conform to the requirements of the regulations for Current Good Manufacturing Practices in the drug industry generally.<sup>34</sup>

Differences in production costs are also unlikely to be the cause of the high price differentials because production costs are only a small part of the final cost of a prescription drug. The typical marginal cost of manufacturing additional volumes of a medication has been estimated to be only 5% of the retail cost.<sup>35</sup> Thus, even large differences in drug production costs would be unlikely to result in the differences in drug prices observed in this study.

## **B. Research and Development Costs**

Drug manufacturers frequently point to the costs of research and development as a justification for high prices. However, differences in research and development costs do not appear to explain the differences in cost between identical human and animal drugs.

According to an industry expert consulted by the minority staff, Dr. Alan Sager of the Boston University School of Public Health:

The observed price differences cannot be explained by differences in research costs. Research is a fixed or sunk cost. Manufacturers do not set their prices based on recovery of these costs. Instead, they set their prices as high as possible in order to maximize revenue and profit.<sup>36</sup>

Moreover, according to industry analysts, pharmaceutical manufacturers are “investing heavily” in research and development of animal drugs.<sup>37</sup> Relative to the size of the markets, drug manufacturers appear to spend approximately as much on research and development of animal drugs as they do on research and development of human drugs. Pfizer, an industry leader in animal drug sales, had revenues of \$1.3 billion from animal drugs in 1998, and spent approximately \$200 million – over 15% of total sales – on research of animal drugs.<sup>38</sup> Pfizer also

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<sup>34</sup> U.S. Food and Drug Administration, *Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration* (1999) (online at <http://www.fda.gov/opacom/morechoices/smallbusiness/blubook.htm#animalprod.html>).

<sup>35</sup> Alan Sager and Deborah Socolar, *Affordable Medications for Americans* (July 27, 1999).

<sup>36</sup> Dr. Alan Sager, Boston University School of Public Health, *Response to Rep. Henry A. Waxman* (Aug. 1999).

<sup>37</sup> Newsweek, *When Pets Pop Pills* (Oct. 11, 1999).

<sup>38</sup> Pfizer, Inc., *1998 Annual Report* (1999); Los Angeles Times, *Animal Drugs Become Big Pet Project for Industry* (Oct. 12, 1999).

spent approximately the same proportion of revenues, 17%, on its drug products intended for sale to humans.<sup>39</sup>

The high research investment in animal drugs is confirmed by the pharmaceutical industry, which states:

All animal health products go through a stringent seven-step process that involves testing to discover a product, testing to approve the product, and testing to monitor the product once it's been approved....Bringing an animal health product to market is a complex process. Only one in 20,000 discovered chemicals ever makes it from the laboratory to the farm. And only one in 200 potential drugs makes it through pre-clinical testing and approval.<sup>40</sup>

## VI. CONCLUSION

The findings in this report are consistent with the results of the two earlier drug pricing studies done at Rep. Allen's request. The first study found that uninsured seniors in Maine pay 96% more for the five most popular prescription drugs used by seniors than favored purchasers such as HMOs and the federal government.<sup>41</sup> The second study found that uninsured seniors in Maine pay 72% more for these prescription drugs than individual purchasers in Canada, and 102% more than individual purchasers in Mexico.<sup>42</sup> All three studies thus reach the same basic finding: drug manufacturers are engaged in systematic price discrimination that adversely affects millions of senior citizens and other consumers who lack prescription drug coverage.

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<sup>39</sup> Pfizer, Inc., *1998 Annual Report* (1999).

<sup>40</sup> Animal Health Institute, *Testing...testing....testing: Food Safety and Animal Drugs* (May 1999).

<sup>41</sup> *Prescription Drug Pricing in the 1st Congressional District in Maine: Drug Companies Profit at the Expense of Older Americans*, *supra* note 12.

<sup>42</sup> *Prescription Drug Pricing in the 1st Congressional District in Maine: An International Price Comparison*, *supra* note 13.

# Appendix A: Information on Popular Prescription Drugs in this Survey

Human Brand Name	Animal Brand Name	Dosage	Average Manufacturer Charge per Dosage		Typical One Month Prescription	Average Manufacturer Charge per Monthly Prescription	
			Animal	Human		Animal	Human
Amoxil	Robamox	250 mg. cap. (human); 200 mg. cap. (animal)	\$0.14/cap.	\$0.17/cap.	90 cap.	\$16.20	\$15.30
Augmentin	Clavamox	125 mg. tab.	\$0.30/tab.	\$0.94/tab.	60 tab.	\$18.00	\$56.40
Bactroban	Bactoderm	2%, 30 gm. (human); 2%, 15 gm. (animal)	\$4.99/15 gm.	\$31.56/30 gm.	30 gm.	\$9.98	\$31.56
Lanoxin (liquid)	Cardoxin LS	50 Fg./ml., 2 oz.	\$6.36	\$25.65	3 gm. active ingredient 30 tab.	\$6.36	\$25.65
Lanoxin (tab.)	NA	0.125 mg	NA	\$0.17/tab.		NA	\$5.10 <sup>43</sup>
Lasix	Lasix	20 mg. tab. (human); 12.5 mg. tab. (animal)	\$0.05/cap.	\$0.16/cap.	60 cap.	\$4.80	\$9.60
Lodine	Etogesic	300 mg. cap./tab.	\$0.42/tab.	\$1.21/cap.	90 cap.	\$37.80	\$108.90
Stadol	Torbugesic	2 mg./ml., 10 ml.	\$25.48	\$61.11	10 ml.	\$25.48	\$61.11
Vasotec	Enacard	5 mg. tab.	\$0.57/tab.	\$0.88/tab.	90 tab.	\$51.30	\$78.55

<sup>43</sup> The manufacturer-level price for thirty 0.125 mg Lanoxin tablets is \$5.10. These 30 tablets contain a total of 3.75 grams of active ingredient. The liquid version of the product contains 3 grams of active ingredient. In order to obtain a direct comparison of prices for these products, the analysis determined the cost of 3 grams of active ingredient in the tablet form. This cost is (3/3.75) \*(\$5.10) = \$4.08.

**Appendix B: Information on Directly Comparable Prescription Drugs in this Survey**

Human Brand Name	Animal Brand Name	Dosage (Tablet or Capsule)	Average Manufacturer Charge per Dosage		Typical One Month Prescription	Average Manufacturer Charge per Monthly Prescription	
			Animal	Human		Animal	Human
Cleocin	Antirobe	75 mg.	\$0.57	\$0.74	30 cap.	\$17.10	\$22.20
Fulvicin U/F	Fulvicin U/F	500 mg.	\$1.28	\$1.22	30 cap.	\$38.40	\$36.60
Lodine	Etogesic	300 mg.	\$0.42	\$1.20	90 cap.	\$37.80	\$108.90
Medrol	Medrol	4 mg.	\$0.13	\$0.67	30 tab.	\$3.90	\$20.10
Robaxin	Robaxin	500 mg.	\$0.25	\$0.51	60 tab.	\$15.00	\$31.20
Robinul	Robinul-V	1 mg.	\$0.49	\$0.50	60 tab.	\$29.40	\$29.98
Vasotec	Enacard	5 mg.	\$0.57	\$0.87	90 tab.	\$51.30	\$78.55
Winstrol	Winstrol-V	2 mg.	\$0.18	\$0.64	30 tab.	\$5.40	\$19.20